MINNTECH®
A Cantel Medical Company

K120306

Rapicide OPA-28
High Level Disinfectant

SEP 27 2012

510(k) Summary

Manufacturer: Minntech Corporation, A Cantel Medical Company

Address: 14605 28th Avenue North
Minneapolis, MN 55447 USA
(763) 533-3300, 763-551-2653 fax

Official Contact: Brent Geiger, MS, RAC
Senior RA Specialist

Trade Name: **Rapicide OPA-28**
Common Name: Liquid Chemical Germicide
Classification Name: Sterilant, Medical Devices
Product Code: MED
Device Class: II
Classification Reg: 880.6885

Date Prepared: January 20, 2012

Minntech Corporation has supplied the following information to the United States Food and Drug Administration to support substantial equivalence of Rapicide OPA-28 to other similar liquid chemical germicide solutions currently cleared for sale in the United States.

1. Device Description

Rapicide OPA-28 is a reusable liquid *ortho*-Phthalaldehyde (OPA) based high level disinfectant solution intended for reprocessing of heat sensitive semi-critical medical devices for which sterilization is not suitable. Rapicide OPA-28 may be used in manual reprocessing or in compatible legally marketed automatic endoscope reprocessors at the appropriate labeled use conditions.

Rapicide OPA-28 is a clear liquid chemical germicide solution with a pH between 7.5 and 8.0. The active microbicidal ingredient *ortho*-Phthalaldehyde is formulated at a nominal concentration of 0.575% together with a solvent, buffers, surfactants, an antifoaming agent and water to create Rapicide OPA-28 solution. Rapicide OPA-28 is labeled with an unopened bottle shelf-life of 24 months, an open bottle use-period of 75 days and a reuse period not to exceed 28 days. The germicide must be used at or above its MRC, as determined by Rapicide OPA-28 test strips, with the indicated immersion time, use temperature and reuse period. Rapicide OPA-28 is supplied in cases containing high density polyethylene plastic bottles. Individual bottles are labeled with all information necessary to use the device safely.

2. Indications for Use

Rapicide OPA-28 is a high level disinfectant solution for reprocessing of heat sensitive semi-critical medical devices for which sterilization is not suitable. Rapicide OPA-28 may be used at or above its minimum recommended concentration (MRC) of 0.35% OPA as determined by Rapicide OPA-28 test strips in manual device reprocessing with an immersion time of at least 10 minutes at a minimum temperature of 20°C for a reuse period not to exceed 28 days. Rapicide OPA-28 may also be used in compatible legally marketed automatic endoscope reprocessors at or above its MRC as determined by Rapicide OPA-28 test strips with an immersion time of at least 5 minutes at a minimum temperature of 25°C for a reuse period not to exceed 28 days.

3. Comparison to Other Devices in Commercial Distribution Within the United States

Rapicide OPA-28 is equivalent in performance and indications to predicate devices Metricide OPA Plus (K070627), Cidex OPA (K030004) and Rapicide (K993042). All of the products are liquid chemical high level disinfectant solutions with equivalent intended use and indications for use. The chemical formulation of Rapicide OPA-28 is similar to that of predicate devices Metricide OPA Plus and Cidex OPA Solution.

4. Summary of Non-Clinical Performance Data

Minntech Corporation has provided testing to show that Rapicide OPA-28 is safe and effective for its intended use based on the requirements listed in FDA's Guidance for Content and Format of Premarket Notification [510(k)] Submission for Liquid Chemical Sterilants/High Level Disinfectants (Jan 2000). The following types of data/information were provided to FDA in support of substantial equivalence to predicate devices and to demonstrate that Rapicide OPA-28 performs as intended.

- Detailed description of physical and chemical properties
- Proposed labeling
- Sporicidal, tuberculocidal, fungicidal, virucidal and bactericidal efficacy
- Simulated-use and in-use tests
- Rinse Residual and biocompatibility
- Toxicity evaluation
- Material compatibility
- Stability
- Test strip performance

5. Conclusion

Minntech Corporation has provided appropriate premarket notification information in the form of a 510(k) to support the substantial equivalence of Rapicide OPA-28 to legally marketed predicate devices. The information and performance data provided indicates that Rapicide OPA-28 is safe and effective for its intended use when used in accordance with the device labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 27 2012

Mr. Brent Geiger, MS, RAC
Senior Regulatory Affairs Specialist
Minntech Corporation, A Cantel Medical Company
14605 28th Avenue North
Minneapolis, Minnesota 55447

Re: K120306
Trade/Device Name: Rapicide OPA-28
Regulation Number: 21 CFR 880.6885
Regulation Name: Liquid Chemical Sterilants / High level Disinfectants
Regulatory Class: II
Product Code: MED
Dated: September 11, 2012
Received: September 11, 2012

Dear Mr. Geiger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

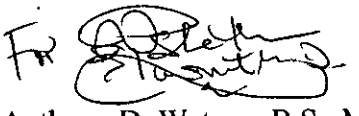
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

MINNTECH®
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Indications for Use

510(k) number (if known):_____

Device Name: **Rapicide OPA-28**

Indications for Use:

Rapicide OPA-28 is a high level disinfectant solution for reprocessing of heat sensitive semi-critical medical devices for which sterilization is not suitable. Rapicide OPA-28 may be used at or above its minimum recommended concentration (MRC) of 0.35% OPA as determined by Rapicide OPA-28 test strips in manual device reprocessing with an immersion time of at least 10 minutes at a minimum temperature of 20°C for a reuse period not to exceed 28 days. Rapicide OPA-28 may also be used in compatible legally marketed automatic endoscope reprocessors at or above its MRC as determined by Rapicide OPA-28 test strips with an immersion time of at least 5 minutes at a minimum temperature of 25°C for a reuse period not to exceed 28 days.

Elizabeth P. Hamilton-Wells
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120306

Prescription Use _____ AND/OR Over-the-Counter Use__X____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)